		<b>Deferred Prosecution Agreement</b>
		CLERKS OFFICE U.S. DIST. COURT
UNITED STATES	FILED	
WESTERN DISTI ABIN	<b>A</b> December 13, 2024	
ADII	LAURA A. AUSTIN, CLERK	
	,	BY: s/ FELICIA CLARK
UNITED STATES OF AMERICA	)	DEPUTY CLERK
<b>v.</b>	) Criminal No.	1:24CR46
MCKINSEY & COMPANY, INC.	)	

#### **DEFERRED PROSECUTION AGREEMENT**

)

1. The United States Attorney's Office for the Western District of Virginia, the United States Attorney's Office for the District of Massachusetts, and the United States Department of Justice's Consumer Protection Branch (collectively, "the United States") and McKinsey & Company, Inc. United States ("MCKINSEY US") and McKinsey & Company, Inc. ("McKinsey Inc.") (collectively, "MCKINSEY"), pursuant to authority granted by their Shareholders Council (also known as the Board of Directors), enter into this agreement. MCKINSEY US is the defendant in this matter. McKinsey Inc. is a party to this agreement but is not a defendant in this matter.

#### **GENERAL PROVISIONS**

- 2. MCKINSEY agrees it will fulfill all obligations set forth in this Agreement and its attachments.
- 3. MCKINSEY will execute and transmit all documents needed to effectuate the terms of this Agreement.
- 4. MCKINSEY agrees it is not, in any way, a "prevailing party." MCKINSEY waives any claim for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.
- 5. For purposes of this agreement, "United States" is as defined above and "United States Government" is the entire federal government.

#### RELEVANT CONSIDERATIONS

6. The United States enters into this Agreement based on the individual facts and circumstances presented by this case, including:

**UNITED STATES** 

- a. the nature and seriousness of the offense conduct, as described in the Agreed Statement of Facts;
- b. MCKINSEY did not receive voluntary disclosure credit because it did not voluntarily and timely disclose to the United States the conduct described in the Agreed Statement of Facts ("Statement of Facts") (attached as Attachment 3);
- c. MCKINSEY received some credit for its cooperation with the United States, by, among other things: (i) providing updates regarding information obtained through its internal investigation; (ii) highlighting documents of interest in voluminous productions, after previously failing to identify certain emails early in the investigation that reflected potential document deletion; and (iii) facilitating interviews;
- d. MCKINSEY engaged in extensive remedial measures, including (i) voluntarily stopping all work in 2019 on any opioid-specific business issues, and later agreeing not to do any work related to the marketing, sale, promotion, or distribution of any controlled substances during the Term of this Agreement; (ii) terminating two senior partners who communicated about deleting opioid-related documents concerning Purdue Pharma L.P.; (iii) hiring a new Chief Legal Officer, Chief Ethics and Compliance Officer, and Head of Internal Audit, all from outside MCKINSEY; (iv) enhancing its new client selection framework and deploying a formalized diligence review and intake process for all clients; (v) strengthening, enhancing, and committing to continue to enhance, its compliance program, policies and procedures, and Code of Conduct; (vi) implementing and providing training to employees on enhanced compliance policies; (vii) establishing compliance and risk monitoring and audit processes; (viii) engaging a firm to independently test key portions of MCKINSEY's enhanced compliance program; and (ix) enhancing its internal reporting, investigations, and risk assessment processes;
- e. MCKINSEY has no prior history of similar misconduct, but (i) McKinsey Inc. entered into civil settlements in 2019 and 2020 with the U.S. Trustee Program to resolve a dispute regarding the adequacy of McKinsey Inc.'s disclosures in connection with certain bankruptcy cases; (ii) a subsidiary of McKinsey Inc., MIO Partners, Inc., agreed in 2021 to pay a civil penalty to the U.S. Securities and Exchange Commission to resolve allegations that it had failed to maintain internal controls reasonably designed to prevent the misuse of material, non-public information; and

- (iii) a subsidiary of McKinsey Inc., McKinsey & Company Africa (Pty) Ltd, entered into a deferred prosecution agreement on December 5, 2024, regarding violations of the Foreign Corrupt Practices Act;
- f. MCKINSEY previously reached multiple settlements to date totaling \$989.9 million relating to its sales and marketing work for Purdue Pharma L.P., including a \$642.4 million settlement with all 50 states, five U.S. territories, and Washington, D.C.; and civil settlements totaling \$347.5 million; and
- MCKINSEY has agreed to continue to cooperate with the United States. g.

#### **CHARGES**

- 7. MCKINSEY US consents to the filing of an Information (attached as Attachment 4) in the United States District Court for the Western District of Virginia in Abingdon, Virginia (referred to herein as the "Court"), charging it with:
  - knowingly and intentionally conspiring with Purdue Pharma L.P. and a. others to aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid prescriptions, in violation of 21 U.S.C. §§ 331(k), 333(a)(1), 353(b)(1), and 18 U.S.C. §§ 2 and 371; and
  - through the acts of a MCKINSEY senior partner, knowingly destroying b. and concealing records and documents with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of any department or agency of the United States and in relation to and contemplation of any such matter, in violation of 18 U.S.C. § 1519.
- MCKINSEY US knowingly waives its right to indictment and gives up its right to be charged by indictment and have a grand jury vote on its probable guilt. MCKINSEY US agrees to venue of the case in the Western District of Virginia. MCKINSEY US knowingly waives any applicable statute of limitations and any legal or procedural defects in the Information.

#### **FACTS**

MCKINSEY stipulates and agrees the facts and allegations set forth in the Information and the facts set forth in the Agreed Statement of Facts are true and correct.

#### **ACCEPTANCE OF RESPONSIBILITY**

10. MCKINSEY accepts and acknowledges responsibility for its conduct and that of its owners, partners, consultants, and employees as set forth in the Information and the Agreed Statement of Facts.

#### **ADMISSIBILITY OF STATEMENTS**

agrees it will neither contest the admissibility of the Agreed Statement of Facts, nor contradict the facts contained within the Information and/or the Agreed Statement of Facts. Further, in any proceeding involving the United States Government, MCKINSEY knowingly waives any right it may have under the Constitution, any statute, rule, or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence, and MCKINSEY stipulates that such statements can be admitted into evidence.

#### AGREED ORDER COMPELLING COMPLIANCE

12. MCKINSEY agrees to the entry of an Agreed Order Compelling Compliance (attached as Attachment 8), as a condition of the United States' agreement to defer prosecution, in which MCKINSEY is ordered to comply with the terms of this Agreement and, in addition to the other remedies available in this Agreement, be subject to the jurisdiction of the Court whether for a proceeding that could result in contempt or any other remedy the Court deems appropriate should MCKINSEY fail to comply with any term of the Agreement. MCKINSEY agrees nothing will divest the Court of jurisdiction, including, but not limited to, any proceeding relating to bankruptcy, insolvency, reorganization, or relief of debtors.

#### **DEFERRAL OF PROSECUTION**

- 13. In consideration of MCKINSEY's remedial actions to date and its willingness to: (a) acknowledge and accept full responsibility for its actions; (b) cooperate in the ongoing criminal investigation of others; (c) demonstrate its future good conduct and full compliance with federal law; and (d) comply with the obligations set forth in this Agreement and its attachments, the United States agrees that upon entry by the Court of the Agreed Order Compelling Compliance it will recommend to the Court that prosecution of MCKINSEY US on the charges set forth in the Information be deferred for the duration of the Term.
- 14. If MCKINSEY fully complies with this Agreement, the United States will not prosecute MCKINSEY or its successors or assigns for any criminal conduct occurring

prior to the date this Agreement is signed based on conduct set forth in the Information and/or Agreed Statement of Facts. However, the United States may use any information gathered during its investigation for any purpose, including, but not limited to, use in contempt proceedings. Nothing prevents the United States from pursuing any action against any individual.

- 15. MCKINSEY expressly waives any and all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution and Federal Rule of Criminal Procedure 48(b) for the Term of this Agreement. MCKINSEY US agrees to join the United States in seeking to exclude, pursuant to 18 U.S.C. § 3161(h)(2), the Term of this Agreement from the time within which trial of the offense charged in the Information must commence, for the purpose of allowing MCKINSEY to demonstrate its good conduct (the joint motion is attached as Attachment 7).
- 16. If MCKINSEY fully complies with all of its obligations under this Agreement, the United States, within 30 days of the expiration of the Term, will seek dismissal with prejudice of the Information filed against MCKINSEY US.

#### **TERM**

- 17. The Term of MCKINSEY's obligations under this Agreement will be five years from the date the Information is filed ("Effective Date"). However, the Term will be extended to include any time prior to MCKINSEY fully complying with all of its commitments, financial and otherwise, set forth in this Agreement.
- 18. MCKINSEY agrees, in the event the United States determines, in its sole discretion, that MCKINSEY has failed to comply with any provision of this Agreement, an extension of the Term may be imposed by the United States, in its sole discretion, for up to an additional 12 month period, without prejudice to the right of the United States to seek any other remedy set forth in this Agreement. Any extension of the Agreement extends all terms of the Agreement, but does not extend the date by which all payments must be made. This paragraph does not, in any way, limit the preceding paragraph.

#### COMPLIANCE AND MANAGING PARTNER CERTIFICATION

- 19. MCKINSEY agrees it will comply with all of its obligations set forth in the attachments to this Agreement, including, but not limited to, Attachments 2A, 2B, and 2C dealing with compliance and certifications.
- 20. On an annual basis, with the first report due 12 months after the Effective Date, McKinsey Inc.'s Managing Partner shall provide a document to the United States Attorney's Office for the Western District of Virginia, the United States Attorney's

certifications will be adjusted accordingly.

Office for the District of Massachusetts, and the Consumer Protection Branch of the United States Department of Justice, certifying, under oath and based on a diligent inquiry, that (a) in the previous 12 month period, MCKINSEY fully complied with this Agreement and its attachments and has not violated federal law; or (b) in the previous 12 month period, MCKINSEY fully complied with this Agreement and its attachments and has not violated federal law with the exception of items on an attached list documenting all non-compliant activity and the steps taken by the Company to remedy such non-compliant activity. The final report will be due 10 days prior to the expiration of the Term and will cover the period of time since the last reporting period, and the

#### FINANCIAL OBLIGATIONS

- 21. MCKINSEY will pay a total of \$650,000,000 (six hundred fifty million dollars) plus interest accrued, as specified herein. This total payment shall be allocated as follows:
  - a. \$323,020,647.75 (three hundred twenty-three million twenty thousand six hundred forty-seven dollars and seventy-five cents) plus interest at a rate of 4.125% per annum computed from July 10, 2024, on any unpaid balance to be paid by MCKINSEY pursuant to the Civil Settlement Agreement (payments designated in table below as "Civil");
  - b. \$231,432,853.25 (two hundred thirty-one million four hundred thirty-two thousand eight hundred fifty-three dollars and twenty-five cents) plus interest at a rate of 4.34% per annum computed from December 1, 2024, on any unpaid balance (payments designated in table below as "Criminal");
  - c. \$93,546,499 (ninety-three million five hundred forty-six thousand four hundred ninety-nine dollars) plus interest at a rate of 4.34% per annum computed from December 1, 2024, on any unpaid balance to be paid by MCKINSEY as forfeiture of proceeds (payments designated in table below as "Forfeiture"); and
  - d. \$2,000,000 (two million dollars) to be paid by MCKINSEY to the Virginia Medicaid Fraud Control Unit to be used for the 25% state match of the Medicaid Fraud Control Unit grant (payment designated in table below as "VA-MFCU").

22. The payments shall be made in the amounts and on the dates set forth in the table below (the "Table of Payments"), as directed by the United States:

TABLE OF PAYMENTS							
		Designation of Payments					
Payment Date	Payment Amount	Civil	Criminal	Forfeiture	VA-MFCU		
12/16/2024	\$175,000,000.00	\$86,967,097.47	\$39,259,653.03	\$46,773,249.50	\$2,000,000.00		
12/16/2025	\$175,000,000.00	\$86,967,097.47	\$72,441,819.36	\$15,591,083.17			
12/16/2026	\$100,000,000.00	\$49,695,484.27	\$34,713,432.56	\$15,591,083.17			
12/16/2027	\$100,000,000.00	\$49,695,484.27	\$34,713,432.56	\$15,591,083.16			
12/16/2028	\$100,000,000.00	\$49,695,484.27	\$50,304,515.74				
TOTAL	\$650,000,000.00	\$323,020,647.75 *	\$231,432,853.25 *	\$93,546,499.00 *	\$2,000,000.00		

<sup>\*</sup>Plus accrued interest as set forth above.

- 23. The entire amount of unpaid financial obligations shall bear simple interest from the dates set forth above until such amount is paid. Such interest shall accrue at the Interest Rate on the basis of the actual number of days elapsed and a year of 365 or 366 days, as the case may be.
- 24. No money paid by MCKINSEY will be returned and MCKINSEY expressly releases any and all claims it may have to the money. MCKINSEY will not file any claim or otherwise contest the payment of money set forth in this Agreement, and it will not assist anyone in asserting a claim to the money.
- 25. Nothing in this Agreement or any related document is an admission by the United States that the amounts paid by MCKINSEY are the maximum amounts that could, in the absence of this Agreement, be recovered from MCKINSEY. If MCKINSEY does not comply with all of its obligations under this Agreement, the United States is not precluded from arguing or presenting evidence that the total amount to be paid by MCKINSEY should be higher.
- 26. MCKINSEY shall notify the United States immediately when it learns that it may not be able to timely pay an amount due pursuant to this Agreement.
- 27. MCKINSEY must notify the United States as soon as reasonably practicable, in writing, of any event (including, but not limited to, sale, merger, dissolution, etc.) that would jeopardize its ability to pay any amounts under this Agreement. If an adverse event (including, but not limited to, sale, merger, dissolution, etc.) would jeopardize MCKINSEY's ability to pay any amounts under this Agreement, or if any payment would cause MCKINSEY to either (a) violate an existing debt covenant for which the holder(s)

will not forbear, forgive or otherwise extend, or (b) incur a negative going concern or viability assessment by its auditors as required by any applicable domestic or foreign corporate governance code, accounting standard or related rule or regulation, MCKINSEY shall notify the United States as soon as reasonably practicable. Should unrelated, unanticipated economic circumstances create a material risk that MCKINSEY may reasonably incur any of the events identified herein, MCKINSEY may request that the United States agree to delay any payment identified in the Table of Payments. The United States may consider such request but is under no obligation to agree to delay any payment.

- 28. MCKINSEY represents and warrants that it has reviewed its financial situation, it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and it reasonably believes it shall remain solvent following payment of the financial obligations set forth in this Agreement. Further, the parties warrant that, in evaluating whether to execute this Agreement, they have (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to MCKINSEY, within the meaning of 11 U.S.C. § 547(c)(l); and (b) concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to, and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which MCKINSEY was or became indebted to on or after the Agreement Date, within the meaning of 11 U.S.C. § 548(a)(1). MCKINSEY agrees its obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and MCKINSEY shall not argue or otherwise take the position in any such case, action, or proceeding that (1) MCKINSEY's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (2) MCKINSEY was insolvent at the time this Agreement was entered into; or (3) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to MCKINSEY. MCKINSEY acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement. MCKINSEY agrees all amounts payable under this Agreement are not dischargeable in bankruptcy and shall be considered debt for a fine, penalty, or forfeiture payable to and for the benefit of a governmental unit pursuant to 11 U.S.C. § 523(a)(7). MCKINSEY will not contest that all forfeiture amounts ordered by the Court against MCKINSEY represent criminal proceeds subject to forfeiture, and as such, the United States' interest in those proceeds arose on the date MCKINSEY received those proceeds pursuant to 21 U.S.C. § 853(c).
- Contemporaneously with execution of this Agreement, MCKINSEY will 29. execute a note in favor of the United States setting forth the amounts due pursuant to this Agreement. The note will indicate that all amounts are due and payable upon demand by the United States. So long as MCKINSEY complies with its obligations in this Agreement

and it is not apparent that MCKINSEY will not timely make a payment, the United States will not demand payment beyond the timely payments required by this Agreement.

- 30. Pursuant to the terms of the Security Agreement (attached as Attachment 6), MCKINSEY agrees to provide the United States, on the Effective Date of this Agreement and all times thereafter, a first priority security interest and lien on accounts receivables or other collateral as provided in the Security Agreement (the "Collateral"), in an aggregate amount equal to, on any date of determination, the lesser of (a) \$300,000,000 (three hundred million dollars) and (b) 110% of the outstanding balance of unpaid obligations. MCKINSEY shall execute and deliver such agreements, financing statements and other collateral documents as may be required from time to time pursuant to the terms of the Security Agreement, including for purposes of granting, maintaining or perfecting the United States' lien on the Collateral. The United States shall release its lien on the Collateral as provided in the Security Agreement.
- 31. MCKINSEY, may, and with no less than five (5) business days prior written notice to the United States, from time to time prepay, without premium or penalty, any unpaid installment in the Table of Payments, together with interest thereon through the date of such prepayment.
- 32. If any payment required to be made by MCKINSEY is not timely made, it becomes obvious that MCKINSEY will not timely make a payment, or MCKINSEY fails to comply with any provision of this Agreement, MCKINSEY will have failed to comply with a provision of this Agreement. Accordingly, the United States, immediately, may collect the entire remaining unpaid amount due plus interest and pursue any or all of the remedies available for failing to comply with a provision of the Agreement.
- 33. Restitution is not applicable. In any event, attempting to determine restitution would be impracticable and administratively infeasible.

#### **FORFEITURE**

34. MCKINSEY agrees to cooperate fully in the forfeiture of the property to be forfeited. MCKINSEY agrees to execute all documents, stipulations, consent judgments, court orders, bills of sale, deeds, affidavits of title, and the like, which are necessary to pass clear title to the United States or otherwise effectuate forfeiture of the property including, but not limited to the Stipulation for Compromise Settlement (Attachment 9B), and Agreed Order of Forfeiture (Attachment 9C), and Motion and Order for Substitute Res (Attachment 9D). MCKINSEY understands and will not object to the United States filing a Verified Complaint for Forfeiture *in rem* (Attachment 9A). MCKINSEY agrees to fully cooperate and to provide truthful testimony on behalf of the United States in any legal action

necessary to perfect the United States' interest, including but not limited to any ancillary hearing in this criminal action or in any civil litigation.

- 35. To the extent that forfeiture pursuant to this Agreement requires MCKINSEY to disgorge wrongfully obtained criminal proceeds, MCKINSEY agrees the forfeiture is primarily remedial in nature. MCKINSEY understands and agrees that forfeiture of this property is proportionate to the degree and nature of the offense committed by MCKINSEY. MCKINSEY freely and knowingly waives all constitutional and statutory challenges in any manner (including direct appeal, habeas corpus, or any other means) to any forfeiture carried out in accordance with this Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. MCKINSEY further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any penalty that may be imposed by the Court.
- 36. MCKINSEY hereby releases and forever discharges the United States Government, its officers, agents, servants and employees, its heirs, successors, or assigns, from any and all actions, causes of action, suits, proceedings, debts, dues, contracts, judgments, damages, claims, and/or demands whatsoever in law or equity that MCKINSEY ever had, now has, or may have in the future in connection with the seizure, detention, and forfeiture of the described assets.

### AGREEMENT NOT TO DO ANY WORK RELATED TO CONTROLLED SUBSTANCES

37. MCKINSEY agrees it will not do any work related to the marketing, sale, promotion, or distribution of controlled substances, as defined in 21 U.S.C. § 802(6), during the Term of this Agreement.

#### **COOPERATION**

38. MCKINSEY will fully cooperate with all investigations and prosecutions, if any, by the United States Government related, in any way, to opioids or obstruction of justice. MCKINSEY's cooperation in the investigation and prosecution of individuals and entities pursuant to this paragraph includes, but is not limited to, using best efforts promptly to secure the attendance and testimony of any current or former shareholder, partner, officer, director, consultant, agent, or employee of MCKINSEY at any meeting or interview or before the grand jury or at any trial or other court proceeding; and truthfully disclosing all factual information, documents, records, or other tangible evidence not protected by a valid claim of privilege or work product. MCKINSEY's cooperation is subject to valid noted claims of (a) attorney-client privilege or (b) the attorney work product doctrine. MCKINSEY expressly understands any information it provides may be used by the United States Government for any purpose.

Exhibit A to Agreed Order Compelling Compliance In re: McKinsey & Company, Inc.

**Deferred Prosecution Agreement** 

39. MCKINSEY will not, through its present or future shareholders, partners, directors, officers, consultants, employees, or agents, (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Agreement or its attachments. If MCKINSEY makes a public statement that in whole or in part contradicts any such statement or provision, MCKINSEY may avoid being in violation of this Agreement by promptly and publicly repudiating such statement. For purposes of this paragraph, the term "public statement" means any statement made or authorized by MCKINSEY's shareholders, directors, officers, partners, consultants, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, (3) communications with clients, (4) communications with all employees of MCKINSEY, (5) posts or messages on any social media platform (including but not limited to "X"), or (6) MCKINSEY's websites. Notwithstanding the above, MCKINSEY may avail itself of any legal or factual arguments available in defending litigation brought by a party other than the United States. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

#### SUCCESSOR LIABILITY

Except as may otherwise be agreed by the parties in connection with a 40. particular transaction, MCKINSEY agrees if, during the term of this Agreement, it undertakes any material change in corporate form, including if it sells, merges, or transfers any portion of its business operations material to MCKINSEY's consolidated operations as they existed as of June 1, 2024, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement unless the United States otherwise agrees in writing. MCKINSEY shall provide notice to the United States at least 30 days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict MCKINSEY from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the United States.

#### REMEDIES

- 41. In addition to other remedies set forth in this Agreement, if the United States, in its sole discretion, determines MCKINSEY (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement; (b) committed a federal or state crime during the term of this Agreement; or (c) failed to comply with any provision of this Agreement, then (1) the United States will not be bound by its agreement not to prosecute MCKINSEY and (2) the United States may, in addition to any other action, file any charges that were filed or could have been filed against MCKINSEY relating to its investigation that led to this Agreement. In such event, MCKINSEY agrees any prosecution not time-barred by the applicable statute of limitations on the Effective Date of this Agreement, including time protected as the result of agreements between the United States and MCKINSEY to toll the applicable statute of limitations, may be commenced against MCKINSEY. Accordingly, MCKINSEY has executed and agrees to be bound by the tolling agreement included as Attachment 5 to this Agreement.
- 42. Should the United States determine that MCKINSEY has failed to comply with any provision of this Agreement AND it seeks to exercise its right to pursue a remedy other than as contemplated by the Agreed Order Compelling Compliance (Attachment 8), the United States shall provide written notice to MCKINSEY addressed to its Chief Legal Officer, and to its outside counsel, Charles Duross, or to any successor MCKINSEY may designate, of the failure to comply and provide MCKINSEY with a 30-day period from the date of receipt of notice in which to make a presentation to the United States to demonstrate that it did comply with all provisions of this Agreement or, to the extent applicable, that the failure to comply should not result in adverse action, including because the failure to comply has been cured by MCKINSEY. The parties expressly understand and agree that:
  - a. MCKINSEY's failure to make the above-noted presentation within such time period, shall be considered an admission that MCKINSEY failed to comply as set forth in the written notice;
  - b. Regardless of the content of the presentation, the United States retains its full discretion to determine if MCKINSEY failed to comply with a provision of this Agreement; and
  - c. The United States' exercise of discretion is not subject to review in any court or tribunal outside of the United States.
- 43. Any available remedy set forth in this Agreement takes precedence over any provision of the Security Agreement.

44. The remedies set forth in this Agreement are cumulative and not mutually exclusive. The United States' election of any of these remedies does not, in any way, terminate MCKINSEY's obligation to comply with the terms of this Agreement. The use of "if" does not mean "if, and only if."

#### **EXCLUSION**

45. MCKINSEY understands that nothing in this Agreement shall resolve or release any administrative action, decision, or proceeding (including, but not limited to, licensing, contracting, and permitting) that the United States Government could initiate as a consequence of entering into this Agreement.

#### ENTITIES NOT BOUND BY THIS AGREEMENT

46. This Agreement does not bind the Tax Division of the United States Department of Justice, any other federal agency, or any state, local, or foreign law enforcement or regulatory agency, or any other authority.

#### WAIVER OF RIGHT TO RECORDS

47. MCKINSEY waives all rights, whether asserted directly or by a representative, to request or receive from the United States and the Virginia Office of the Attorney General Medicaid Fraud Control Unit any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, the Privacy Act of 1974, 5 U.S.C. § 552a, or the Virginia Freedom of Information Act, Va. Code § 2.2-3700-3714.

#### LIABILITY OF INDIVIDUALS

48. Nothing in this Agreement resolves, in any way, any liability of any individual.

#### **PUBLIC STATEMENT**

49. Within 24 hours of the Effective Date, MCKINSEY shall place, and maintain for a period of three years, on the home page of MCKINSEY's publicly accessible company websites, a conspicuous public link titled "Deferred Prosecution Agreement Relating to Our Work for Purdue Pharma." The link shall directly access (a) a public statement detailing MCKINSEY's contrition for its conduct, (b) this Agreement (including all attachments), the Agreed Statement of Facts, and the Information. After three years, the

link and documents referenced above must remain readily accessible on MCKINSEY's public web page dedicated to opioid-related information for the duration of the Term of the Agreement. The public statement must be approved by the United States prior to the execution of this Agreement.

#### NOTIFICATION TO MCKINSEY PERSONNEL

- 50. MCKINSEY shall:
- a. Require that each member of the Executive Leadership team, Shareholders Council, and Client Service Risk Committee, read the Information, Agreed Statement of Facts, and this Agreement;
  - Each person holding a role in one of the categories set forth above on the Effective Date, who is not on extended leave, shall complete this requirement within 30 days of the Effective Date;
  - For the duration of the Term, each person holding a role in one of the categories set forth above who was on extended leave on the Effective Date or who holds a role in one of the above categories after the Effective Date shall complete this requirement within 30 days of returning from leave or becoming a member, as applicable.
- b. Develop and provide mandatory global training regarding this resolution, including the facts of the conduct, a root cause analysis, remediation efforts, and ongoing compliance obligations for all client-serving consultants, and all risk, compliance, and legal personnel;
  - Each person in one of the categories above who is employed on the Effective Date and not on extended leave shall complete this requirement within 90 days of the Effective Date;
  - For the duration of the Term, each person in one of the categories listed above who was on extended leave on the Effective Date or was employed after the Effective Date shall complete this requirement within 90 days of returning from leave or becoming employed, as applicable.
- 51. MCKINSEY shall maintain all training materials used for the above-described training and records documenting that the requirements of this section of the Agreement have been met. Upon request, McKinsey shall provide these materials and records to the United States.

#### **ENTIRE AGREEMENT**

52. This Agreement and its attachments set forth all the terms of the agreement between MCKINSEY and the United States. No amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the United States, an attorney for MCKINSEY, and a duly authorized representative of MCKINSEY.

#### SATISFACTION WITH REPRESENTATION

53. MCKINSEY has discussed the terms of the Agreement and all matters pertaining to it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice and has no dissatisfaction or complaint with its attorneys' representation.

#### **EFFECT OF SIGNATURE**

54. MCKINSEY understands its signature on this Agreement constitutes a binding offer by it to enter into this Agreement. MCKINSEY understands the United States has not accepted MCKINSEY's offer until each signatory for the United States has signed the Agreement.

#### **AUTHORITY TO ENTER AGREEMENT**

55. MCKINSEY US and McKinsey Inc. each acknowledge its acceptance of this Agreement by the signature of its counsel and Authorized Corporate Representative. A copy of the resolution by McKinsey Inc.'s Shareholders Council authorizing each entity's Authorized Corporate Representative to execute this Agreement and all other documents to resolve this matter on behalf of MCKINSEY US and McKinsey Inc. is attached as Attachment 1.

Ag	re	ed	to:

McKinsey & Company, Inc. United States:

BY:

Jonathan B. Stonim

Deputy General Counsel Head of Legal, Americas

Partner of McKinsey & Company, Inc.

Vice President of McKinsey & Company, Inc. United States

Authorized Corporate Representative of McKinsey & Company, Inc. United States

Date

Document 2

Pageid#: 21

McKinsey & Company, Inc.:

BY:

Pierre M. Gentin

Chief Legal Officer

Senior Partner of McKinsey & Company Inc.

Authorized Corporate Representative of McKinsey & Company, Inc.

Counsel has fully explained to the Shareholders Council of McKinsey & Company, Inc. the facts and circumstances of the prosecution and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the clients. McKinsey & Company, Inc. and McKinsey & Company, Inc. United States fully understand the terms and conditions of this Agreement, and their decision to enter into this Agreement is knowing and voluntary. The execution and entry into this Agreement by McKinsey & Company, Inc. and McKinsey & Company, Inc. is done with Counsel's consent.

Charles E. Duross

Brian-K. Kidd

Katherine E. Driscoll

Morrison & Foerster LLP

Counsel for McKinsey & Company, Inc. United States and McKinsey & Company, Inc.

Jones L. Bernard

Hogan Lovells US LLP

Counsel for McKinsey & Company, Inc. United States and McKinsey & Company, Inc.

Ingrid S. Martin

Todd & Weld LLP

Counsel for McKinsey & Company, Inc. United States and McKinsey & Company, Inc.

The United States Attorney's Office for the Western District of Virginia:

BY:

Christopher R. Kavanaugh United States Attorney

Churtester & Planningh

KRISTEN M. ECHEMENDIA

Senior Trial Counsel

Department of Justice, Civil Division Commercial Litigation Branch

KIMBERLY M. BOLTON

Special Assistant United States Attorney Special Assistant United States Attorney Assistant Attorney General

Medicaid Fraud Control Unit

Virginia Office of the Attorney General Virginia Office of the Attorney General

December 13, 2024

Date

RANDY RAMSEYER

Assistant United States Attorney

Randy Kamseyer

Assistant Attorney General Medicaid Fraud Control Unit

The United States Attorney's Office for the District of Massachusetts:

BY:

Joshua S. Levy

United States Attorney

AMANDA MASSELAM STRACHAN

Chief, Criminal Division

WILLIAM B. BRADY

Assistant United States Attorney

The United States Department of Justice, Consumer Protection Branch:

RV

Amanda N. Liskamm

Director

Anthony Nardozzi

Deputy Director, Criminal

Any L. DeLine
Assistant Director

JESSICA C. HARVEY

Trial Attorney

STEVEN R. SCOTT

Trial Attorney

Filed 12/13/24

Page 20 of 75

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Corporate Certifications** 

**COMPANY OFFICER'S CERTIFICATE FOR** MCKINSEY & COMPANY, INC. UNITED STATES

I have read this Agreement and carefully reviewed every part of it with outside

counsel for McKinsey & Company, Inc. United States ("MCKINSEY US"). I understand

the terms of this Agreement and voluntarily agree, on behalf of MCKINSEY US, to each

of its terms. Before signing this Agreement, I consulted outside counsel for MCKINSEY

US. Counsel fully advised me of the rights of MCKINSEY US, of possible defenses, of

the Sentencing Guidelines' provisions, and of the consequences of entering into this

Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors

of MCKINSEY US. I have advised and caused outside counsel for MCKINSEY US to

advise the Board of Directors of MCKINSEY US fully of the rights of MCKINSEY US,

of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of

entering into this Agreement.

No promises or inducements have been made other than those contained in this

Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any

person authorizing this Agreement on behalf of MCKINSEY US, in any way to enter into

this Agreement. I am also satisfied with outside counsel's representation in this matter. I

certify that I am a Partner and the Deputy General Counsel, Head of Legal, Americas, for

Exhibit A (Attachment 1) to Agreed Order Compelling Compliance

In re: McKinsey & Company, Inc.

Page 1 of 14

Filed 12/13/24

Page 21 of 75

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Certifications

McKinsey & Company, Inc. and that I am Vice President of and have been duly authorized by McKinsey US to execute this Agreement on behalf of McKinsey US.

Date: 12/10/24

Bv

Jonathan B. Stonim

Deputy General Counsel, Head of Legal, Americas, Partner of McKinsey & Company, Inc. and Vice President and Authorized Corporate Representative of McKinsey & Company, Inc. United States

Filed 12/13/24

Page 22 of 75

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Corporate Certifications** 

COMPANY AUTHORIZED REPRESENTATIVE'S CERTIFICATE FOR MCKINSEY & COMPANY, INC.

I have read this Agreement and carefully reviewed every part of it with outside

counsel for McKinsey & Company, Inc. ("McKinsey Inc."). I understand the terms of this

Agreement and voluntarily agree, on behalf of McKinsey Inc., to each of its terms. Before

signing this Agreement, I consulted outside counsel for McKinsey Inc. Counsel fully

advised me of the rights of McKinsey Inc., of possible defenses, of the Sentencing

Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors

for McKinsey Inc. I have advised and caused outside counsel for McKinsey Inc. to advise

the Board of Directors fully of the rights of McKinsey Inc., of possible defenses, of the

Sentencing Guidelines' provisions, and of the consequences of entering into this

Agreement.

No promises or inducements have been made other than those contained in this

Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any

person authorizing this Agreement on behalf of McKinsey Inc., in any way to enter into

this Agreement. I am also satisfied with outside counsel's representation in this matter. I

Exhibit A (Attachment 1) to Agreed Order Compelling Compliance

In re: McKinsey & Company, Inc.

Page 3 of 14

Page 23 of 75

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Certifications

certify that I am a Senior Partner and Chief Legal Officer for McKinsey Inc. and that I have been duly authorized by McKinsey Inc. to execute this Agreement on behalf of McKinsey Inc.

Date: 12/16/24

By: No Pierre M. Gentin

Senior Partner and Chief Legal Officer of McKinsey & Company, Inc. and Authorized Corporate Representative of McKinsey & Company, Inc.

Filed 12/13/24

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Corporate Certifications** 

### CERTIFICATE OF COUNSEL FOR MCKINSEY & COMPANY, INC. UNITED STATES

I am counsel for McKinsey & Company, Inc. United States ("MCKINSEY US") in the matter covered by this Agreement. In connection with such representation, I have examined relevant MCKINSEY US documents and have discussed the terms of this Agreement with MCKINSEY US's Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of MCKINSEY US has been duly authorized to enter into this Agreement on behalf of MCKINSEY US and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of MCKINSEY US and is a valid and binding obligation of MCKINSEY US. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors of MCKINSEY US and the Deputy General Counsel, Head of Legal, Americas, Partner for McKinsey & Company, Inc., Jonathan B. Slonim, who is a Vice President of MCKINSEY US and has been duly authorized as the representative of MCKINSEY US. I have fully advised them of the rights of MCKINSEY US, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of MCKINSEY US to enter into this

Exhibit A (Attachment 1) to Agreed Order Compelling Compliance

In re: McKinsey & Company, Inc.

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 30

Filed 12/13/24

Page 25 of 75

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Certifications

Agreement, based on the authorization of the Board of Directors of MCKINSEY US, is an

informed and voluntary one.

Date: 12/10/24

Charles E. Duross

Morrison & Foerster LLP

Counsel for McKinsey & Company,

Inc. United States

Filed 12/13/24

Page 26 of 75

Attachment I to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Certifications

### CERTIFICATE OF COUNSEL FOR MCKINSEY & COMPANY, INC.

I am counsel for McKinsey & Company, Inc. ("McKinsey Inc.") in the matter covered by this Agreement. In connection with such representation, I have examined relevant McKinsey Inc. documents and have discussed the terms of this Agreement with McKinsey Inc.'s Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of McKinsey Inc. has been duly authorized to enter into this Agreement on behalf of McKinsey Inc. and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of McKinsey Inc. and is a valid and binding obligation of McKinsey Inc. Further, I have carefully reviewed the terms of this Agreement with McKinsey Inc.'s Board of Directors and Senior Partner and Chief Legal Officer, Pierre M. Gentin. I have fully advised them of the rights of McKinsey Inc., of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of McKinsey Inc. to enter into this Agreement, based on the authorization of McKinsey Inc.'s Board of Directors, is an informed and voluntary one.

Date: 12/10/24

Charles E. Duross

Morrison & Foerster LLP

Counsel for McKinsey & Company,

Inc.

By

# <u>CERTIFICATE OF CORPORATE RESOLUTIONS FOR</u> <u>MCKINSEY & COMPANY, INC. UNITED STATES</u>

WHEREAS, McKinsey & Company, Inc. United States ("MCKINSEY US") has been engaged in discussions with the United States Attorney's Office for the Western District of Virginia, the United States Attorney's Office for the District of Massachusetts, and the United States Department of Justice's Consumer Protection Branch (collectively the "United States") regarding issues arising in relation to the conduct described in the attached Statement of Facts;

WHEREAS, in order to resolve such discussions, it is proposed that MCKINSEY US agree to certain terms and obligations of a deferred prosecution agreement among MCKINSEY US and the United States (the "Agreement"); and

WHEREAS, Deputy General Counsel, Head of Legal, Americas, Partner of McKinsey & Company, Inc. ("McKinsey Inc."), and Vice President and duly authorized corporate representative of MCKINSEY US, Jonathan B. Slonim, together with outside counsel for MCKINSEY US (the "Counsel"), have advised the Board of Directors of MCKINSEY US of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of agreeing to such terms and obligations of this Agreement.

Therefore, the Board of Directors of MCKINSEY US has RESOLVED that:

1. MCKINSEY US (a) acknowledges the filing of a two-count Information charging MCKINSEY US with one misdemeanor count of knowingly and intentionally conspiring with Purdue Pharma L.P. and others to aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid

Exhibit A (Attachment 1) to Agreed Order Compelling Compliance

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Corporate Certifications** 

prescriptions, in violation of 21 §§ 331(k), 333(a)(1), 353(b)(1), and 18 U.S.C. §§ 2 and 371, and one felony count of knowingly destroying and concealing, through the acts of a MCKINSEY US senior partner, records and documents with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of any department or agency of the United States and in relation to and contemplation of any such matter, in violation of 18 U.S.C. § 1519; (b) undertakes certain obligations under this Agreement; and (c) agrees to accept a monetary penalty totaling \$650,000,000, and to pay such a penalty according to the following allocation: (i) \$323,020,647.75 pursuant to the Civil Settlement Agreement; (ii) \$231,432,853.25 pursuant to the Criminal penalty; (iii) \$93,546,499 as forfeiture of proceeds; and (iv) \$2,000,000 to the Virginia Medicaid Fraud Control Unit.

2. MCKINSEY US accepts the terms and conditions of this Agreement, including, but not limited to: (a) a knowing waiver of MCKINSEY US's right to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of any objection with respect to venue and consents to the filing of the Information against MCKINSEY US, as provided under the terms of this Agreement, in the United States District Court for the Western District of Virginia in Abingdon, Virginia; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to conduct known to the United

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 34 Filed 12/13/24

Page 29 of 75

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Corporate Certifications** 

States prior to the date on which this Agreement was signed, that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. Deputy General Counsel, Head of Legal, Americas, Partner of McKinsey Inc., and Vice President and authorized corporate representative for MCKINSEY US, Jonathan B. Slonim, is hereby authorized, empowered, and directed, on behalf of MCKINSEY US, to agree to certain terms and obligations of this Agreement, substantially in such form as reviewed by the Board of Directors of MCKINSEY US with such changes as Counsel may approve;

4. Deputy General Counsel, Head of Legal, Americas, Partner of McKinsey Inc., and Vice President and authorized corporate representative for MCKINSEY US, Jonathan B. Slonim, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate, and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. Jonathan B. Slonim or any officer of MCKINSEY US is, hereby authorized, empowered and directed to take such actions and execute and deliver such documents as may be necessary or appropriate to effectuate the intent and purposes of the foregoing resolutions.

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 35 Filed 12/13/24

Page 30 of 75

Attachment 1 to Deferred Prosecution Agreement
United States v. McKinsey & Company, Inc. United States

Date: 12/10/2024

**Corporate Certifications** 

By:

Eric Kuteher

President of McKinsey & Company, Inc.

**United States** 

# <u>CERTIFICATE OF CORPORATE RESOLUTIONS FOR</u> <u>MCKINSEY & COMPANY, INC.</u>

WHEREAS, McKinsey & Company, Inc. ("McKinsey Inc.") has been engaged in discussions with the United States Attorney's Office for the Western District of Virginia, the United States Attorney's Office for the District of Massachusetts, and the United States Department of Justice's Consumer Protection Branch (collectively the "United States") regarding issues arising in relation to the conduct described in the attached Statement of Facts;

WHEREAS, in order to resolve such discussions, it is proposed that McKinsey Inc. agree to certain terms and obligations of a deferred prosecution agreement between McKinsey & Company, Inc. United States ("MCKINSEY US") and the United States (the "Agreement"); and

WHEREAS, the Senior Partner and Chief Legal Officer for McKinsey Inc., Pierre M. Gentin, together with outside counsel for McKinsey Inc. (the "Counsel"), have advised the Board of Directors of McKinsey Inc. of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of agreeing to such terms and obligations of this Agreement.

Therefore, the Board of Directors of McKinsey Inc. has RESOLVED that:

1. McKinsey Inc. (a) acknowledges the filing of a two-count Information charging MCKINSEY US with one misdemeanor count of knowingly and intentionally conspiring with Purdue Pharma L.P. and others to aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid

Exhibit A (Attachment 1) to Agreed Order Compelling Compliance

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Corporate Certifications** 

prescriptions, in violation of 21 U.S.C. §§ 331(k), 333(a)(1), 353(b)(1), and 18 U.S.C. §§ 2 and 371, and one felony count of knowingly destroying and concealing, through the acts of a MCKINSEY US senior partner, records and documents with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of any department or agency of the United States and in relation to and contemplation of any such matter, in violation of 18 U.S.C. § 1519; (b) undertakes certain obligations under this Agreement; and (c) agrees to accept a monetary penalty totaling \$650,000,000, and to pay such a penalty according to the following allocation: (i) \$323,020,647.75 pursuant to the Civil Settlement Agreement; (ii) \$231,432,853.25 pursuant to the Criminal penalty; (iii) \$93,546,499 as forfeiture of proceeds; and (iv) \$2,000,000 to the Virginia Medicaid Fraud Control Unit;

2. McKinsey Inc. accepts the terms and conditions of this Agreement, including, but not limited to: (a) a knowing waiver of MCKINSEY US's right to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of any objection with respect to venue and consents to the filing of the Information against MCKINSEY US, as provided under the terms of this Agreement, in the United States District Court for the Western District of Virginia in Abingdon, Virginia; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to conduct known to the United States

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 38 Filed 12/13/24

Page 33 of 75

**Corporate Certifications** 

Attachment 1 to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

prior to the date on which this Agreement was signed, that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

- 3. Senior Partner and Chief Legal Officer for McKinsey Inc., Pierre M. Gentin, is hereby authorized, empowered, and directed, on behalf of McKinsey Inc., to agree to certain terms and obligations of this Agreement substantially in such form as reviewed by the Board of Directors of McKinsey Inc. with such changes as Counsel may approve;
- 4. Senior Partner and Chief Legal Officer for McKinsey Inc., Pierre M. Gentin, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate, and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the purpose and intent of the foregoing resolutions; and
- 5. Pierre M. Gentin or any officer of McKinsey Inc. is, hereby authorized, empowered and directed to take such actions and execute and deliver such documents as may be necessary or appropriate to effectuate the intent and purposes of the foregoing resolutions.

Date: Dec 10th, 2024

оу. 🖊

Robert Sternfels

President of McKinsey & Company, Inc.

Attachment 2A to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Compliance Program

### **CORPORATE COMPLIANCE PROGRAM**

In order to address any deficiencies in its internal controls, compliance policies and procedures, and Code of Conduct (collectively, "Compliance Program") regarding compliance with the federal conflicts of interests statutes; the Federal Acquisition Regulation; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"); obstruction statutes; federal laws prohibiting aiding, abetting, and conspiring with entities and individuals engaged in violations of federal law; and all regulations associated with these provisions ("Relevant Law"), McKinsey & Company, Inc., and its subsidiaries and affiliates, including, but not limited to, McKinsey & Company, Inc. United States (collectively "McKinsey" or the "Company"), on behalf of itself and its subsidiaries and affiliates, agrees to continue to conduct, in a manner consistent with all of its obligations under the Deferred Prosecution Agreement ("Agreement"), appropriate reviews of its existing, recently implemented, internal controls, compliance policies and procedures, and Code of Conduct.

Where necessary and appropriate, the Company agrees to adopt a new, or to modify its existing, Compliance Program, to ensure it maintains an effective compliance program designed, implemented, and enforced to effectively deter and detect violations of the Relevant Law. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance policies and procedures, and Code of Conduct:

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

In re: McKinsey & Company, Inc.

Attachment 2A to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Compliance Program

### Commitment to Compliance

1. The Company will ensure that the Global Managing Partner, members of the Shareholders Council, and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the Relevant Law and the Company's Compliance Program and demonstrate rigorous adherence by example. The Company will also ensure that all levels of management, in turn, reinforce those standards and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations at all levels of the Company.

#### Policies and Procedures

- 2. The Company will develop and promulgate a clearly articulated and visible corporate policy against violations of the Relevant Law, which policy shall be memorialized in a written compliance policy or policies.
- 3. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the Relevant Law and the Company's Compliance Program, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the Relevant Law by personnel at all levels of the Company. These policies and procedures shall apply to all partners, officers, and employees and as necessary or appropriate, outside parties acting on behalf of the Company, such as agents, consultants, authorized representatives, distributors, contractors, suppliers, and joint venture partners

Attachment 2A to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Compliance Program

(collectively, "Agents and Business Partners"). The Company shall notify all employees

that compliance with the policies and procedures is the duty of all individuals at all levels

of the Company.

4. The Company will ensure that it has a system of policies and procedures,

including a system of internal controls, reasonably designed to ensure that the Company

does not itself violate the Relevant Law or provide or assist clients with the implementation

of plans, advice, and/or strategies that violate the Relevant Law. This system shall be

designed to provide reasonable assurances that:

a. the Company creates and maintains a risk assessment process to identify high-

risk engagements using a standardized framework ("Client Service Risk Assessment"),

which requires an assessment of the following factors before performing any work for

a client or potential client:

i. Country: Assess the level of risk in the country of activity and ensure

adherence to the Company's policies on travel, immigration, and international trade

controls (sanctions and exports);

ii. Institution: Check risk factors relating to the potential client institution,

including any material, sustained, or substantiated concerns relating to its integrity

or reputation, including any relevant past misconduct by the client or proposed

client, including prior criminal, civil, and regulatory resolutions, adverse media

searches for allegations of illegal, unethical, or fraudulent conduct, and evaluation

of the ethical attributes and internal controls of the client or potential client;

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

iii. Topic: Engage with clients on topics where the Company is confident in its

ability to deliver meaningful impact and with which the Company is comfortable

being associated externally;

iv. Individual: Assess concerns related to individual client leaders and people

in positions of ownership or control, including any material and substantiated

concerns relating to their integrity, reputation, or background; and

v. Operational considerations: Ensure any engagement complies with legal

and regulatory requirements and with all of the Company's policies and avoid work

that risks exposing the Company and its employees to undue risk;

b. the Client Service Risk Assessment approval process will be mandatory in

evaluating whether to approve an engagement, and if so, a mitigation process by which,

for approved engagements deemed to be high-risk engagements, there are appropriate

written guardrails implemented and monitored;

c. the Client Service Risk Assessment shall also include mandatory procedures to

address the following:

i. for any new client, ensure that a responsible partner and accountable senior

partner follow all client diligence procedures before any engagement can begin,

including approval by both a managing partner in the relevant geography and sector;

and

ii. for any current or prospective client, apply the Client Service Risk

Assessment to assess the risk of serving the potential client, including whether the

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

Company may perform the work contemplated by the engagement, and assess if any

safeguards must be imposed before the work can commence. The responsible

partner must conduct both assessments and the accountable senior partner must

review and approve the assessments;

d. the Company creates and maintains a mandatory enhanced risk assessment and

due diligence process prior to engaging with any client, current or prospective, that

itself or any subsidiary or affiliate has, in the five years prior to the engagement proposal

either been convicted of a crime, resolved any criminal investigation, or been under

supervision by a court or government as a result thereof ("Tier 1 Entity"), or has been

found liable in or resolved any civil or regulatory matter brought by any government

entity or been under supervision by a court or government as a result thereof for a

violation of law with material consequences to the client involving a risk to the public

("Tier 2 Entity"), which will require:

i. a review of such current or prospective Tier 1 Entity or Tier 2 Entity's past

misconduct, including charging documents, resolution agreements, and statements

of facts if they exist, and an assessment of any ongoing regulatory scrutiny relating

to the Tier 1 Entity or Tier 2 Entity;

ii. an automatic escalation to the Client Service Risk Committee ("CSRC") for

any Tier 1 Entity and written CSRC approval, along with approvals by the Chief

Legal Officer and Global Chief Ethics and Compliance Officer, before proceeding

to do any further work for the Tier 1 Entity;

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

In re: McKinsey & Company, Inc.

Page 5 of 17

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 44 Filed 12/13/24

Page 39 of 75

Attachment 2A to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Compliance Program

iii. quarterly compliance reports of the Tier 1 review and approval process by

the CSRC, Chief Legal Officer, and Global Chief Ethics and Compliance Officer;

iv. maintenance of Company records documenting that these requirements have

been met and, if an engagement is accepted, the reasons for accepting the

engagement and the names of the individuals who approved acceptance of the

engagement; and

v. legal and compliance personnel, under the supervision of the Chief Legal

Officer and Global Chief Ethics and Compliance Officer, have ongoing engagement

with the Client Service Team ("CST"), as set forth below in section (f) in more

detail, while the Tier 1 Entity or Tier 2 Entity continues to be served by the

Company until five years have elapsed since the entity, or any subsidiary or affiliate

of the entity, was subject to the terms of an agreement resolving an investigation or

under court supervision.

e. the Company creates and maintains centralized responsibility and accountability

for all client engagements to ensure such engagements are appropriately reviewed to

determine if they involve a high-risk engagement, a Tier 1 Entity, or a Tier 2 Entity,

and the responsible partner shall ensure that the Company's risk assessment analysis is

completed in the Company's client in-take software, or equivalent, and that the

completeness and accuracy of that assessment is confirmed by the accountable senior

partner;

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

In re: McKinsey & Company, Inc.

Page 6 of 17

Corporate Compliance Program

f. the Company creates and maintains a process, under the supervision of the Chief

Legal Officer and Global Chief Ethics and Compliance Officer, that requires:

i. that, if the Company enters into any engagement involving a Tier 1 Entity or

Tier 2 Entity, before proceeding with such engagement, the Company shall conduct

a review of the client's past conduct, including applicable charging documents,

resolution agreements, and statements of facts if they exist;

ii. that, if the Company enters into any high-risk engagement or an engagement

involving a Tier 1 Entity, the CST shall report quarterly by client to the CSRC

regarding the material recommendations the CST has made to the client, and address

any material potential future recommendations so that the CSRC can evaluate

whether any adjustments to the guidelines pursuant to which the CST is operating

is necessary, including whether to continue working on the engagement;

iii. that the CSRC raise questions or concerns, if any, regarding the CST's client

service to the Chief Legal Officer and Global Chief Ethics and Compliance Officer,

who may consult with external counsel, if necessary and appropriate, and also may

direct that adjustments be made to the guidelines pursuant to which the CST is

operating, including whether to continue working on an engagement, to mitigate the

risk of violations of the Relevant Law: and

iv. that the Company maintain records documenting the names and roles of each

person involved in the process described above and that the requirements set forth

in this paragraph have been met;

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

g. during the term of the Agreement, McKinsey must maintain the Client Service Risk Assessment process, the CSRC processes and procedures, and the oversight by the Chief Legal Officer and Global Chief Ethics and Compliance Officer outlined in Paragraphs 4(a) to 4(f) above;

- h. McKinsey maintains a centralized document storage system ("Storage System") such as a document management system or a file sharing platform;
  - i. unless prohibited by applicable state, federal, or foreign law, McKinsey:
  - i. requires its partners and employees, to create and maintain a final working papers file ("Final Working Papers File") relating to client engagements on the Storage System. The Final Working Papers File shall include:
    - (1) documentation setting forth the scope of services, fees, and legal terms of the arrangement, such as:
      - (a) Memorandum of Confirmation describing scope and fees;
      - (b) consulting agreement, Master Service Agreement, or Statement of Work;
        - (c) written client acknowledgment of receipt of above documentation;
      - (d) any subsequently agreed modifications, extensions, or renewals; and
      - (e) documentation showing the client's acceptance of the above (e.g., emails with client, signed .pdfs);

Corporate Compliance Program

(2) key interim deliverables that support or explain how the final deliverables were developed (e.g., interim SteerCo or client check-in documents);

- (3) final deliverables, including any deliverables specified in a client contract or agreement;
- (4) documentation of any client disagreement (e.g., email, memorandum) and how such disagreement was resolved; and
  - (5) invoices or financial statements shared with the client;

ii. retains all Final Working Papers, except for documents exclusively stored by the client, for a minimum of seven years for all engagements. McKinsey shall ensure that such materials may be promptly accessed and produced upon the request of the United States Government; and

iii. retains all communications (including but not limited to instant message, chat, or text) exchanged on any McKinsey-licensed electronic mail, messaging platform (i.e., currently Slack, Teams, and Zoom Chat), including attachments, for a minimum of seven years for all engagements. McKinsey shall ensure that such materials may be promptly accessed and produced upon the request of the United States Government;

### j. McKinsey will also:

i. implement a training and certification program designed (a) to prevent and prohibit improper deletion of communications relating to McKinsey business, and

Corporate Compliance Program

(b) to encourage all communications relating to McKinsey business to occur on

McKinsey-licensed platforms described in Paragraph 4(i)(iii) above; and

ii. require all client-serving consultants to retain all communications relating to

McKinsey business that occur outside of McKinsey-licensed platforms (including

but not limited to WhatsApp, Signal, and Telegram) during the term of the

Agreement, and further require client-serving consultants to certify compliance with

this requirement on an annual basis;

k. McKinsey implements a written policy requiring the termination of any

employee that engages in obstruction of justice, or attempts to do so;

1. the Company timely discloses to the United States Government client any

current or prior engagement in which a neutral and detached third-party, aware of all

the facts, would reasonably believe the engagement creates an actual or potential

conflict of interest, based upon either (a) Federal Acquisition Regulation Subpart 9.5 or

(b) circumstances in which the Company is advising or in the past three years has

advised any client on work that is or was directly related to the work the Company

would perform for the United States Government client;

i. the Company will disclose any such actual or potential conflict when

submitting a written proposal to the United States Government client in response to

a government-issued request for proposal, even when not required by the terms of a

solicitation, including when McKinsey has not identified an actual or potential

organizational conflict of interest;

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

ii. in all responses to government-issued requests for proposal, McKinsey shall

provide a disclosure identifying the breadth of work performed by the Company and

inform the United States Government of circumstances in which McKinsey

provides or has provided consulting services to commercial institutions across all

industries (including the specific industries relevant to the particular agency and/or

services at issue in the solicitation from the United States Government); and

iii. upon request from a Contracting Officer for additional information, the

Company shall provide such information and, if it is unable to do so because of

confidentiality restrictions or another reason, will notify the Contracting Officer

and, if appropriate, withdraw the proposal from consideration by the United States

Government if the Contracting Officer determines that any concerns have not been

appropriately addressed;

m. the Company creates and maintains an approach to compensation (including, but

not limited to, salaries, bonuses, benefits in-kind, pension contributions, and other

benefits) of its partners, officers, employees, and Agents and Business Partners

reasonably designed to avoid financial incentives motivating such individuals to engage

in, promote, or tolerate violations of the Relevant Law;

n. the Company does not hire Agents and Business Partners for the purpose of

engaging in any activity that the Company itself may not engage in under the terms of

this Agreement, including this Compliance Program;

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

o. the Company creates and maintains performance evaluations of partners, officers, and employees that consider adherence to the Company's Compliance Program, and completion of associated training of the same; and

p. the Company incorporates ethics and compliance considerations into candidate assessments and the recruiting process.

#### Periodic Risk-Based Review

5. The Company will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of the Company.

6. The Company shall review its compliance policies and procedures designed to reduce the prospect of violations of the Relevant Law or the Company's Compliance Program no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company and its clients.

#### Proper Oversight and Independence

7. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's Compliance Program regarding the Relevant Law. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Shareholders Council, or any appropriate committee of the Shareholders

Corporate Compliance Program

Council, and shall have an adequate level of stature and autonomy from management as

Pageid#: 51

well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

8. The Company will implement mechanisms designed to ensure that its

Compliance Program is effectively communicated to all partners, officers, relevant

employees, and, where necessary and appropriate, Agents and Business Partners. These

mechanisms shall include: (a) periodic training for all partners and officers; all employees

in positions of leadership or trust or in positions that require such training (e.g., regulatory,

sales, marketing, legal, compliance); all employees who provide or implement advice to

clients; and, where necessary and appropriate, Agents and Business Partners; and (b)

corresponding certifications by all such partners, officers, employees, and Agents and

Business Partners, certifying compliance with the training requirements. The Company

will conduct training in a manner tailored to the audience's size, sophistication, or subject

matter expertise and, where appropriate, will discuss prior compliance incidents.

9. The Company will maintain, or where necessary establish, an effective

system for providing guidance and advice to partners, officers, employees, and, where

necessary and appropriate, Agents and Business Partners, on complying with the

Company's compliance policies and procedures regarding the Relevant Law, including

when they need advice on an urgent basis.

Reporting and Investigation of Misconduct

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

10. The Company will maintain, or where necessary establish, an effective

system for internal and, where possible, confidential reporting by, and protection of,

partners, officers, employees, and, where appropriate, Agents and Business Partners

concerning violations of the Relevant Law or the Company's Compliance Program.

11. The Company will maintain, or where necessary establish, an effective and

reliable process with sufficient resources for responding to, investigating, and documenting

allegations of violations of the Relevant Law or the Company's Compliance Program

regarding the Relevant Law. The Company will handle the investigations of such

complaints in an effective manner, including routing the complaints to proper personnel,

conducting timely and thorough investigations to determine root causes, and following up

with appropriate corrective actions and remediation, including disciplinary actions, where

necessary.

Enforcement and Discipline

12. The Company will implement mechanisms designed to effectively enforce

its Compliance Program, including appropriately incentivizing compliance and

disciplining violations.

13. The Company will institute appropriate disciplinary procedures to address,

among other things, violations of the Relevant Law and the Company's Compliance

Program by the Company's partners, officers, consultants, and employees. Such

procedures should be applied consistently, fairly, and in a manner commensurate with the

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

violation, regardless of the position held by, or perceived importance of, the partner,

officer, consultant, or employee.

14. The Company shall implement procedures to ensure that where misconduct

is discovered, reasonable steps are taken to remedy the harm resulting from such

misconduct, and to ensure that appropriate steps are taken to prevent further similar

misconduct, including assessing the Company's Compliance Program and making

modifications necessary to ensure its effectiveness.

Third-Party Relationships

15. The Company will institute appropriate risk-based due diligence and

compliance requirements regarding the Relevant Law that pertain to the retention and

oversight of Agents and Business Partners, including:

a. conducting adequate due diligence with respect to the risks posed by the use of

Agents and Business Partners, including their reputations and relationships, if any, with

regulatory authorities and agencies;

b. informing Agents and Business Partners of the Company's commitment to

abiding by the Relevant Law and of the Company's Compliance Program; and

c. seeking a reciprocal commitment from Agents and Business Partners.

16. The Company also will engage in ongoing risk-based monitoring of Agents

and Business Partners through updated due diligence, training, audits, and/or annual

compliance certifications by the third party.

Exhibit A (Attachment 2A) to Agreed Order Compelling Compliance

Corporate Compliance Program

17. Where necessary and appropriate, the Company will include standard provisions in agreements, contracts, and renewals thereof with Agents and Business Partners that are reasonably calculated to prevent violations of the Relevant Law, which may, depending upon the circumstances, include: (a) undertakings relating to compliance with the Relevant Law; (b) rights to conduct audits of the facilities, documents, and records of Agents and Business Partners to ensure compliance with the foregoing; and (c) rights to terminate Agents and Business Partners as a result of any breach of the Relevant Law, the Company's Compliance Program, or the representations and undertakings related to such

### Mergers and Acquisitions

- 18. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate due diligence regarding the Relevant Law by legal and compliance personnel.
- 19. The Company will ensure that the Company's Compliance Program apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:
  - a. train the shareholders, officers, consultants, employees, and Agents and Business Partners consistent with Paragraph 8 above on the Relevant Law and the Company's Compliance Program; and

In re: McKinsey & Company, Inc.

matters.

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 55

Filed 12/13/24

Page 50 of 75

Attachment 2A to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

Corporate Compliance Program

b. where warranted, conduct an audit of all newly acquired or merged businesses as quickly as practicable concerning compliance with the Relevant Law.

#### Monitoring, Testing, and Remediation

20. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance policies and procedures regarding the Relevant Law that are designed to evaluate and improve their effectiveness in preventing and detecting violations of the Relevant Law and the Company's Compliance Program, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company and its clients. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful and thorough root cause analysis and timely and appropriately remediate to address the root causes.

21. The Company will have the effectiveness of the preceding elements of its Compliance Program audited by an outside independent entity, on an annual basis, and provide the entity's findings to the United States in its annual report (see Attachment 2B).

**Compliance Reporting Requirements** 

# **COMPLIANCE REPORTING REQUIREMENTS**

McKinsey & Company, Inc., and its subsidiaries and affiliates, including, but not limited to, McKinsey & Company, Inc. United States (collectively "McKinsey" or the "Company"), agrees that it will report to the United States Attorney's Office for the Western District of Virginia, the United States Attorney's Office for the District of Massachusetts, and the United States Department of Justice's Consumer Protection Branch (collectively, the "United States") periodically. Unless otherwise directed by the United States in writing, the Company shall transmit all copies of all work plans, reports, certifications, and other notices to the United States as required herein by electronic mail to Consumer.Compliance@usdoj.gov and to any additional email addresses provided by the United States. The subject line of the email must begin with the Company's name. In the event that electronic mail is unavailable, the notice may be sent by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail to an address provided by the United States.

During the Term of the Deferred Prosecution Agreement ("the Agreement"), the Company shall review, test, and update its internal controls, compliance policies and procedures, and Code of Conduct described in Attachment 2A. The Company shall be required to: (a) conduct an initial review and submit a first report, and (b) conduct and prepare at least four follow-up reviews and reports, as described below. Prior to conducting each review, the Company shall be required to prepare and submit a work plan for the review. The Company shall also be required to submit additional types of reports on a

Exhibit A (Attachment 2B) to Agreed Order Compelling Compliance In re: McKinsey & Company, Inc.

**Compliance Reporting Requirements** 

periodic basis, as described below. The Company shall also, if requested by the United

States during the Term, provide additional information, including documents, or meet with

the United States regarding remediation, implementation, and testing of its internal

controls, compliance policies and procedures, and Code of Conduct described in

Attachment 2A.

In conducting the reviews, the Company shall undertake the following activities,

among others: (a) inspection of relevant documents, including the Company's current

policies, procedures, and training materials concerning compliance with the federal

conflicts of interests statutes; the Federal Acquisition Regulation; Federal Food, Drug, and

Cosmetic Act, 21 U.S.C. § 301 et seg. ("FDCA"); obstruction statutes; federal laws

prohibiting aiding, abetting, and conspiring with entities and individuals engaged in

violations of federal law; and all regulations associated with these provisions ("Relevant

Law"); (b) inspection and testing of the Company's systems, internal controls, compliance

policies and procedures, and Code of Conduct, including record keeping and internal audit

procedures; (c) meetings with, and interviews of, relevant current and, where appropriate,

former partners, officers, employees, consultants, partners, agents, and other persons; and

(d) analyses, studies, and comprehensive testing of the Company's compliance program.

Written Work Plans, Reviews, Reports, and Certifications

1. The Company shall conduct a first review and prepare a first report, followed

by at least four follow-up reviews and reports.

Exhibit A (Attachment 2B) to Agreed Order Compelling Compliance

**Compliance Reporting Requirements** 

2. Within sixty (60) calendar days after the Effective Date of the Agreement,

the Company shall, after consultation with the United States, prepare and submit a written

work plan to address the Company's first review. The United States shall have thirty (30)

calendar days after receipt of the written work plan to provide comments, which the

Company shall incorporate into its written work plan.

3. With respect to each follow-up review and report, after consultation with the

United States, the Company shall prepare a written work plan within forty-five (45)

calendar days after the submission of the prior report, and the United States shall provide

comments within thirty (30) calendar days after receipt of the written work plan, which the

Company shall incorporate into its written work plan.

4. All written work plans shall identify with reasonable specificity the activities

the Company plans to undertake to review and test each element of its compliance program,

as described in Attachment 2A.

5. Any disputes between the Company and the United States with respect to any

written work plan shall be decided by the United States in its sole discretion.

6. No later than twelve (12) months after the Effective Date of the Agreement,

the Company shall submit to the United States a first written report setting forth: (1) a

complete description of its remediation efforts to date; (2) a complete description of the

testing conducted to evaluate the effectiveness of the compliance program and the results

of that testing; and (3) its proposals to ensure that the compliance program is reasonably

designed, implemented, and enforced so that the program is effective in deterring and

**Compliance Reporting Requirements** 

detecting violations of the Relevant Law; a certification from the Company's Global

Managing Partner and Global Chief Ethics and Compliance Officer, in the form of

executing the document attached as Attachment 2C to the Agreement, shall accompany the

report. The written report and certification will be deemed a material statement and

representation by the Company to the executive branch of the United States for purposes

of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the Western

District of Virginia, the District of Massachusetts, and the District of the District of

Columbia. With prior written approval of the United States, the Company may extend the

time period for issuance of the first report and certification.

Follow-up Reviews, Reports, and Certifications

7. The Company shall undertake at least four follow-up reviews, reports, and

certifications, incorporating the views of the United States on the Company's prior reviews,

reports, and certifications, to further monitor and assess whether the Company's

compliance program is reasonably designed, implemented, and enforced so that it is

effective at deterring and detecting violations of the Relevant Law.

8. Each follow-up review, report, and certification shall be completed and

delivered to the United States no later than twelve (12) months after the submission of the

prior report and certification, except that the final follow-up review, report, and

certification shall be completed and delivered to the United States no later than thirty (30)

calendar days before the end of the Term.

Exhibit A (Attachment 2B) to Agreed Order Compelling Compliance

**Compliance Reporting Requirements** 

9. As part of the final follow-up report, the Company shall include a sustainability plan that describes the Company's objectives and methodology for maintaining a compliance program that is effective at deterring and detecting violations of the Relevant Law.

10. With prior written approval of the United States, the Company may extend the time period for submission of any of the follow-up reports and certifications.

# Additional Reporting Requirements

11. The Company shall submit written reports to the United States concerning Reportable Events on a quarterly basis. A Reportable Event is any matter that, after a reasonable opportunity to conduct an appropriate review or investigation of the allegations, a reasonable person would consider a material violation of the Relevant Law. A Reportable Event may be the result of an isolated event or a series of occurrences. The written report shall include: (a) whether any Reportable Events have been determined to have occurred during the preceding calendar quarter, and providing updated information about Reportable Events that the Company determined to have occurred during any prior calendar quarter, as may be necessary in the reasonable determination of the Company or at the United States' request; (b) a description of the Reportable Event, including the relevant facts, the positions of the persons involved, and the legal authorities implicated; (c) a description of the Company's actions taken to investigate and correct the Reportable Event; and (d) a description of any further steps the Company plans to take to address the Reportable Event and prevent it from recurring. The written reports shall be submitted to the United States

**Compliance Reporting Requirements** 

no later than fifteen (15) calendar days after the end of each calendar quarter (that is, by

January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter

ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the

calendar quarter ending September 30), excepting any calendar quarter that ends within

thirty (30) calendar days of the end of the Term.

Additional Information and Meetings During the Term

12. Upon request of the United States in its sole discretion, the Company shall

provide to the United States additional information or documents regarding the Company's

compliance-related improvements, processes, and controls. The Company's cooperation

pursuant to this Paragraph is subject to applicable law, and regulations, as well as valid

claims of attorney-client privilege or attorney work product doctrine; however, the

Company must provide to the United States a log of any information or cooperation that is

not provided based on an assertion of law, regulation, or privilege, and the Company bears

the burden of establishing the validity of any such assertion.

13. Throughout the Term of the Agreement, whenever the United States deems

it appropriate in its sole discretion, representatives from the Company and the United States

will meet to discuss the status of the review and reporting obligations, and any suggestions,

comments, or improvements the Company may wish to discuss with or propose to the

United States.

Confidentiality of Submissions

Exhibit A (Attachment 2B) to Agreed Order Compelling Compliance

Case 1:24-cr-00046-RSB-PMS

Document 2 Pageid#: 62

t 2 Filed 12/13/24

Page 57 of 75

Attachment 2B to Deferred Prosecution Agreement United States v. McKinsey & Company, Inc. United States

**Compliance Reporting Requirements** 

14. Submissions by the Company, including the work plans and reports, will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the submissions could discourage cooperation or impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the submissions and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent the United States determines in its sole discretion that disclosure would be in furtherance of the United States' discharge of its duties and responsibilities or is otherwise required by law.

Document 2 Pageid#: 63 Filed 12/13/24

Page 58 of 75

Attachment 2C to Deferred Prosecution Agreement
United States v. McKinsey & Company, Inc. United States

Compliance Certification

# **CERTIFICATION**

To: United States Department of Justice

Consumer Protection Branch Attention: Corporate Compliance

United States Attorney's Office for the District of Massachusetts

United States Attorney's Office for the Western District of Virginia

Re: Deferred Prosecution Agreement Disclosure Certification

The undersigned certify, pursuant to Attachments 2A and 2B of the Deferred Prosecution Agreement ("DPA") effective on [DATE], by and between the United States Attorney's Office for the Western District of Virginia, the United States Attorney's Office for the District of Massachusetts, and the United States Department of Justice's Consumer Protection Branch (collectively "the United States") and McKinsey & Company, Inc., and its subsidiaries and affiliates, including, but not limited to, McKinsey & Company, Inc. United States (collectively "McKinsey" or the "Company"), that the undersigned are aware of the Company's reporting obligations under Attachment 2B of the DPA and have reviewed the Company's [first/second/third/fourth/fifth] written work plan and compliance report. The undersigned further certify that to the best of the undersigned's knowledge based on a reasonable inquiry, the Company's [first/second/third/fourth/fifth] compliance report has disclosed to the United States all information required pursuant to Attachment 2B of the DPA, which includes (1) a complete description of the Company's remediation efforts to date; (2) a complete description of the testing conducted to evaluate the effectiveness of the compliance program and the results of that testing; and (3) the Company's proposals to ensure that its compliance program is reasonably designed, implemented, and enforced so that the program is effective in deterring and detecting violations of the federal conflicts of interests statutes; the Federal Acquisition Regulation; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"); obstruction statutes; federal laws prohibiting aiding, abetting, and conspiring with entities and individuals engaged in violations of federal law; and all regulations associated with these provisions ("Relevant Law"). The undersigned further certify that to date, to the best of the undersigned's knowledge based on a reasonable inquiry, the Company has disclosed to the United States all Reportable Events as required by Attachment 2B of the DPA.

The undersigned further acknowledge and agree that the reporting requirements contained in Attachment 2B of the DPA and the representations contained in this certification

Document 2 Pageid#: 64

Filed 12/13/24

Page 59 of 75

Attachment 2C to Deferred Prosecution Agreement
United States v. McKinsey & Company, Inc. United States

Compliance Certification

constitute a significant and important component of the DPA and the United States' determination of whether the Company has satisfied its obligations under the DPA.

The undersigned hereby certify that the undersigned are the Global Managing Partner and Global Chief Ethics & Compliance Officer, of the Company and have been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the Western District of Virginia, the District of Massachusetts, and the District of the District of Columbia. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the Western District of Virginia, the District of Massachusetts, and the District of the District of Columbia.

By:		Dated:	
	[NAME]		
	Global Managing Partner		
	McKinsey & Company, Inc.		
By:		Dated:	
	[NAME]		
	Global Chief Ethics and		
	Compliance Officer		
	McKinsey & Company, Inc.		

Agreed Statement of Facts

# UNITED STATES DISTRICT COURT WESTERN DISTRICT OF VIRGINIA ABINGDON

UNITED STATES OF AMERICA	)	
	)	
v.	)	Criminal No.
	)	
MCKINSEY & COMPANY, INC.	)	
UNITED STATES	)	

### **AGREED STATEMENT OF FACTS**

- I. Organization of McKinsey & Company, Inc., United States and work with Purdue Pharma, L.P.
- 1. The defendant, McKinsey & Company, Inc. United States (MCKINSEY) is a Delaware corporation with its principal place of business in New York, New York. MCKINSEY is an indirect wholly owned subsidiary of McKinsey & Company, Inc. (McKinsey Inc.), a New York Corporation. McKinsey Inc. is a global management consulting firm, founded in 1926 in Chicago, Illinois and with offices in over 130 cities in more than 65 countries.
- 2. MCKINSEY supports private sector clients throughout the United States. MCKINSEY recruits consultants with a wide variety of backgrounds including from the most elite universities in the world. MCKINSEY consultants often work directly with clients' senior management (C-Suite) and boards of directors.

Agreed Statement of Facts

3. MCKINSEY is organized into practice groups led by senior partners of the firm. One of these was the firm's Pharmaceutical and Medical Products (PMP) practice. For years, MCKINSEY worked with several pharmaceutical companies concerning their manufacture and sale of opioids, including Purdue Pharma L.P., Company 1, Company 2, and Company 3. Between 2004 and 2019, MCKINSEY contracted with Purdue Pharma L.P. on 75 different engagements in the United States.

- 4. Purdue Pharma L.P. is a U.S.-based, privately held pharmaceutical limited partnership, established in Delaware with its principal place of business in Connecticut (together with its affiliates, "Purdue Pharma"). Purdue Pharma manufactured, distributed, and sold the extended-release opioid drugs OxyContin, Butrans, and Hysingla. Purdue Pharma sales representatives marketed these drugs through in-person sales calls until in or about February 2018, when Purdue Pharma laid off the bulk of its sales force and ceased all in-person opioid marketing, although it continues online marketing and offers prescription savings cards for OxyContin and other opioid products to this day.
- 5. OxyContin is an extended-release oxycodone tablet. Oxycodone is an opioid agonist with a morphine milligram equivalent (MME) of 1.5 and a high potential for abuse. Oxycodone is a Schedule II narcotic controlled substance.
- 6. In 1995, OxyContin was approved by the United States Food and Drug Administration (FDA) for the "management of moderate to severe pain in patients who

<sup>&</sup>lt;sup>1</sup> MME is a value that represents the potency of an opioid dose relative to morphine.

Agreed Statement of Facts

require treatment with an oral opioid analgesic for more than a few days." In 2001, FDA approved a revised label for OxyContin, noting OxyContin "is intended for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time."

- 7. A report that Purdue Pharma authored and shared with MCKINSEY in July 2009 stated that OxyContin "currently accounts for 34% of opioid scripts in the US. However, generics are exerting pressure on branded products such that OxyContin is losing share at a rate of 2 points per year."
- 8. In 2010, OxyContin was reformulated with abuse-deterrent properties. MCKINSEY worked with Purdue Pharma to obtain approval of the abuse-deterrent formulation by the FDA. The label still noted OxyContin's ongoing abuse liability, that it could be abused, and was subject to criminal diversion. ("OxyContin contains oxycodone, which is a Schedule II controlled substance with an abuse liability similar to morphine. OxyContin, like morphine and other opioids used for analgesia, can be abused and is subject to criminal diversion.")
- 9. In April 2013, the FDA approved new labeling for OxyContin. The revised OxyContin label read: "OxyContin is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment where alternative treatment options are inadequate" and indicated "the product has physical and chemical properties that are expected to make abuse by injection difficult and to reduce abuse via the intranasal route." The label further noted, however: "[a]buse may occur by taking intact tablets in

Agreed Statement of Facts

Agreed Statement of Facts

quantities greater than prescribed or without legitimate purpose, by crushing and chewing or snorting the crushed formulation, or by injecting a solution made from the crushed formulation.... The data from the clinical study, along with support from the in vitro data, also indicate that OxyContin has physicochemical properties that are expected to reduce abuse via the intranasal route. However, abuse of OxyContin by these routes, as well as by the oral route is still possible." When MCKINSEY received news that the FDA had approved the revised label, a MCKINSEY consultant sent an email to another MCKINSEY consultant saying "[w]e did it."

10. At all relevant times, the sale of OxyContin was approved by the FDA, and it was lawful for licensed medical professionals to prescribe OxyContin to patients for only a medically valid purpose. OxyContin continues to be a prescription drug that is sold lawfully in the United States. Prescribing OxyContin for illegitimate purposes fueled the opioid crisis and continues to be a public health problem in the United States.

### II. The FDA and the Food, Drug, and Cosmetic Act

11. The FDA is responsible for protecting the health and safety of the American public by ensuring, among other things, that pharmaceutical drugs are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA regulates the manufacturing, labeling, and distribution of medical devices shipped or received in interstate commerce and enforces the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (FDCA).

Agreed Statement of Facts

- 12. The FDCA prohibits, among other things, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 331(a).
- 13. The FDCA defines labeling to include "all labels and other written, printed, or graphic matter . . . accompanying [a drug]." 21 U.S.C. § 321(m).
- 14. The FDCA provides that a drug is misbranded "[i]f its labeling [was] false or misleading in any particular." 21 U.S.C. § 352(a). The FDCA further provides that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual." 21 U.S.C. § 321(n).
- 15. OxyContin was a drug within the meaning of the FDCA. 21 U.S.C. § 321(g)(1).

#### III. MCKINSEY's engagements with Purdue Pharma

16. From approximately 2002 to 2003, Purdue Pharma was the subject of a public congressional investigation related to abuse and diversion of OxyContin. In December 2003, the General Accounting Office (GAO) issued findings that, among other things, Purdue Pharma's marketing of OxyContin was overly aggressive and exacerbated

Agreed Statement of Facts

OxyContin's abuse and diversion. The GAO's report also explained that "OxyContin is the most abused single-entity prescription product according to those DEA state and divisional offices that report OxyContin abuse." The report further stated, in part, that "DEA field offices continue to report OxyContin as a drug of choice among abusers." It also stated, "[w]e agree with DEA that Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force and multiple promotional approaches to encourage physicians, including primary care specialists to prescribe OxyContin as an initial opioid treatment for noncancer pain, and that these efforts may have contributed to these problems. We also agree that Purdue marketed OxyContin as having a low abuse liability, but we noted that this was based on information in the original label approved by FDA."

- 17. Shortly thereafter, in 2004, MCKINSEY and Purdue Pharma executed a Master Consulting Agreement, which formed the basis of MCKINSEY's retention as a consultant for Purdue Pharma. Thereafter, for each engagement or project, the parties executed a Statement of Services to the Master Consulting Agreement that detailed the specific terms and plan for each individual project, including project objectives and deliverables. As an outside consultant, MCKINSEY advised Purdue Pharma regarding what steps Purdue Pharma should take in connection with each particular engagement.
- 18. Over the course of 75 engagements from 2004 through 2019 and against the backdrop of a nationwide opioid crisis, MCKINSEY worked with Purdue Pharma on a variety of topics, including how to improve revenues from OxyContin and later

Agreed Statement of Facts

reformulated OxyContin, achieve cost reductions, develop an M&A strategy, improve R&D redesign, and enhance organizational governance and management. Purdue Pharma, in turn, paid MCKINSEY approximately \$93,546,499 (ninety-three million five hundred forty-six thousand four hundred ninety-nine dollars) over that fifteen-year period.

- 19. On or about February 9, 2004, two months after the GAO findings, MCKINSEY presented an outline of a proposal to Purdue Pharma entitled, "Purdue's Imperative Defining a Future of Growth." In that outline, MCKINSEY noted to Purdue Pharma that they had "been on the ground for ~10 days" and had "a better perspective on how [MCKINSEY] might help [Purdue Pharma]." MCKINSEY advised Purdue Pharma to "refocus" on a list of priority items, including "agree[ing] on a set of targeted deep dives to resolve key strategic issues, redesign[ing] selected processes or driv[ing] cost savings in specific areas." Among these was "[d]riving OxyContin performance (resetting targets and coverage model, creating segment-specific messaging and materials)."
- 20. As of February 2004, Purdue Pharma was the subject of federal and state criminal and civil investigations.
- 21. During the time MCKINSEY served as a consultant for Purdue Pharma, MCKINSEY worked closely with Purdue Pharma leadership. At times, MCKINSEY consultants interacted directly with Purdue Pharma's board of directors (Purdue Pharma Board), which was dominated by one family (the Family). MCKINSEY consultants had high-level access to employees at Purdue Pharma; occupied office space at Purdue Pharma's headquarters in Stamford, Connecticut, down the hallway from the Family and

Agreed Statement of Facts

C-Suite; and went on several "ride-alongs" with Purdue Pharma sales representatives, accompanying them on sales calls to potential and then-current prescribers of OxyContin.

MCKINSEY consultants and Purdue Pharma worked side by side to develop marketing messages and increase OxyContin sales, including by using data analytics.

- 22. MCKINSEY knew the risks and dangers associated with OxyContin, a powerful and addictive opioid. MCKINSEY also knew that Purdue Pharma's affiliate and its top executives had previously pled guilty to federal crimes relating to the marketing and promotion of OxyContin. Nevertheless, MCKINSEY chose to continue working with Purdue Pharma to improve sales of OxyContin, among other engagements.
- 23. In fact, between 2013 and 2014, MCKINSEY designed strategies to help Purdue Pharma identify which prescribers the Purdue Pharma sales force should call on to increase OxyContin prescriptions. This included a strategy to identify which current OxyContin prescribers (referred to as High Value Prescribers) would likely generate the greatest number of additional prescriptions if called on by Purdue Pharma's sales force. MCKINSEY recommended the use of factors including the existing volume of OxyContin prescriptions, historic preference for generic drugs, willingness to change from one brand of drug to another, and medical specialty to identify High Value Prescribers. Focusing sales calls on High Value Prescribers resulted in reformulated OxyContin prescriptions for uses that were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and that were often diverted for uses that lacked a legitimate medical purpose. MCKINSEY recommended and worked with Purdue Pharma to implement a plan to detail

**Agreed Statement of Facts** 

these High Value Prescribers, some of which were writing 25 times as many reformulated OxyContin prescriptions as similarly situated peers, because it knew that detailing these prescribers was effective in producing more reformulated OxyContin prescriptions, thereby increasing Purdue Pharma's revenue.

### IV. MCKINSEY's knowledge of Purdue Pharma's 2007 criminal conviction

24. In 2007, a Purdue Pharma affiliate company pled guilty to misbranding OxyContin, from 1996 through 2001, by falsely marketing it as less addictive, less subject to abuse and diversion, and less likely to cause dependence and withdrawal than other pain medications. Purdue Pharma and its affiliate also agreed to pay more than \$600 million, of which more than \$100 million was paid to settle civil False Claims Act liability for knowingly causing the submission of false claims to federal healthcare programs for OxyContin. In addition, Purdue Pharma's then president, general counsel, and medical director each pled guilty to misbranding in violation of the FDCA, a criminal offense, and collectively paid a total of \$34.5 million in monetary penalties. During engagements, each of those executives had offices near the conference room where MCKINSEY employees were stationed at Purdue Pharma's headquarters.

25. As part of the 2007 criminal resolution, Purdue Pharma also entered a fiveyear corporate integrity agreement (CIA) with the Department of Health and Human Services, Office of the Inspector General (HHS-OIG). During its term, the CIA placed restrictions on Purdue Pharma's sales and marketing of OxyContin. Purdue Pharma

Agreed Statement of Facts

determined that some MCKINSEY consultants were "Responsible Covered Persons" under, and therefore subject to, the terms of the CIA.

26. After the 2007 guilty pleas of the Purdue Pharma affiliate and certain executives, MCKINSEY partners maintained close contact with Purdue Pharma. In an email dated June 22, 2007, MCKINSEY Senior Partner 1 wrote to other MCKINSEY partners, including MCKINSEY Senior Partners 2 and 3, about Purdue Pharma: "[M]any touches over past few weeks/months...mxf [sic] – [referring to then Purdue Pharma CEO Michael Friedman] setting up introduction meeting with new ceo...."

#### V. MCKINSEY worked with Purdue Pharma to prepare draft REMS

- 27. In 2007, Congress enacted legislation allowing the FDA to require Risk Evaluation and Mitigation Strategies (REMS) for prescription drugs with addictive properties to ensure the benefits of those drugs outweigh the risks.
- 28. MCKINSEY knew that if the FDA created a REMS with restrictive requirements for opioids, a significant decline of OxyContin sales could result.
- 29. The FDA began to require REMS for various drugs starting in March 2008. Before the FDA required Purdue Pharma to submit a REMS for its abuse deterrent formulation of OxyContin in late 2008, the FDA had never required a REMS for an opioid drug.
- 30. On or about October 3, 2008, the FDA sent a letter to Purdue Pharma outlining the required elements for a proposed REMS by Purdue Pharma, including a

Agreed Statement of Facts

Medication Guide, Elements to Assure Safe Use (ETASU), an implementation system, a communication plan, and a timetable for assessments.

- 31. In an October 2008 confidential memorandum for Purdue Pharma's CEO (Purdue Pharma Executive 1), MCKINSEY outlined its efforts to "work with your core team to partner with them to develop their respective sections of the REMS plan." MCKINSEY wrote: "The FDA's increasingly risk conservative position, has resulted in REMS requirements across indications. For controlled substances, recent communications recommend that the FDA take a broader approach in examining opioids as an entire class. Our interpretation is that this is an aggressive attempt by the agency to address diversion, abuse, and misuse (e.g., high dosages to opioid naïve patients). The potential complication of the approach is that it may unduly limit access to patients who need pain relief." MCKINSEY proposed working with Purdue Pharma to "[d]evelop a fact base and business case that is most effective in meeting [Purdue Pharma's] common objectives with the [FDA] to ensure appropriate use by patients and to prevent access by non-patients."
- 32. On October 23, 2008, MCKINSEY Consultant 1 emailed MCKINSEY's Senior Partners 1 and 2 about MCKINSEY's work with Purdue Pharma, including on the REMS. MCKINSEY Consultant 1 relayed that she had spoken with Purdue Pharma's CEO who was "aware of the critical role we are playing in pulling REMs together and is very appreciative." MCKINSEY Consultant 1 also noted that two Purdue Pharma Board members had approached a member of Purdue Pharma leadership and "blessed' him to do whatever he thinks is necessary to 'save the business." As for Purdue Pharma's broader

Agreed Statement of Facts

strategy, MCKINSEY Senior Partner 1, MCKINSEY Senior Partner 2 and MCKINSEY Consultant 1 emailed about the importance of "get[ting] to the board." MCKINSEY Senior Partner 2 emailed Senior Partner 1, "[Senior Partner 1] maybe you can just call [Family Member 1] and see how he is feeling."

- 33. As part of its work to advise Purdue Pharma on the development of the REMS, MCKINSEY noted it was going to flesh out two REMS variants: "Option A: literal version which follows exactly what the FDA has stated in their letter" or "Option B: 'to the spirit' version, which follows the letter where possible, but where it becomes problematic, go for something that's in line with the spirit of what the FDA is asking for."
- 34. The FDA adopted the less restrictive REMS that resulted in high-dose OxyContin remaining subject to the same oversight as lower dose opioids. It further prevented a moratorium on extended-release opioids. The REMS additionally made training for prescribers voluntary and not mandatory.
- 35. On October 31, 2008, MCKINSEY prepared the first draft of the proposed REMS for OxyContin, which included all elements required by the FDA: (1) a draft medication guide explaining the benefits and risks of OxyContin that Purdue Pharma would distribute to providers to give to every patient prescribed OxyContin; (2) required training for providers and patients; (3) required certification in a program called PROVIDE (Purdue's Responsible Opioid Verification, Intervention, Dispensing, and Evaluation), which was intended to teach prescribers about OxyContin and risk management; (4) a certification program in which prescribers, dispensers, and patients had to be enrolled and

Agreed Statement of Facts

certified in order to prescribe, dispense, or receive OxyContin; (5) training or education about proper use and an attestation of receipt and understanding of that training; (6) a communication plan to support implementation of the REMS program, which required Purdue Pharma to provide a letter and other educational materials to healthcare providers; (7) databases of certified prescribers, dispensers, and patients maintained by Purdue Pharma; and (8) a timeline for submitting assessments at 18 months, 3 years, and 7 years following approval, and every 4 years thereafter.

- 36. On November 5, 2008, MCKINSEY convened a "blue ribbon panel" of independent experts to discuss REMS for reformulated OxyContin, including consultants, doctors, regulatory professionals, and academics to advise on REMS for Purdue Pharma's proposal to the FDA. The panel suggested that having a coalition of industry participants working together to develop uniform REMS would be beneficial for the entire medical industry, including patients.
- 37. On November 14, 2008, in a public meeting unrelated to OxyContin, the Director of the Division of Anesthesia, Analgesia, and Addiction Products at the FDA stated that the FDA was "still in the infancy of understanding what our authorities are under the new law in regard to REMS . . . the one clear voice that we have on this is that it really would be appropriate to have all the companies who have potent opioids work together to have some type of REMS program."
- 38. On December 4, 2008, days before Purdue Pharma was scheduled to submit its already finalized proposed individual REMS, the FDA sent a letter to Purdue Pharma

Agreed Statement of Facts

requesting that Purdue Pharma not submit REMS while the FDA considered class-wide REMS—a uniform program for all products in a drug class.

- 39. On March 3, 2009, the FDA met with manufacturers of extended release and long-acting opioid medications to discuss the requirement for a class-wide REMS. In response, 25 branded and generic pharmaceutical companies that marketed long-acting and extended-release opioids formed a consortium, called the Industry Working Group (IWG), to develop and propose industry-wide REMS for the class of Extended Release/Long-Acting opioids, including reformulated OxyContin.
- 40. MCKINSEY later provided technology support to Purdue Pharma relating to the implementation of REMS but did not provide technology support to the IWG.
- 41. The FDA approved the final class-wide REMS on July 9, 2012. The FDA ultimately adopted the IWG's REMS, which was different from what MCKINSEY originally proposed. For example, unlike the proposed REMS drafted by MCKINSEY, the adopted class-wide REMS did not include any communication plan, certification, verification, patient registry, or database of certified prescribers, dispensers, and patients.

# VI. MCKINSEY worked with Purdue Pharma to enhance "Brand Loyalty" for OxyContin and protect market share

42. On May 25, 2009, Purdue Pharma engaged MCKINSEY to "help protect, defend and accelerate OxyContin performance at a time of change, including the new formulation launch and new competitor entry." According to the contract between MCKINSEY and Purdue Pharma, this effort was focused on developing a "set of messages

Agreed Statement of Facts

and tactics for OxyContin to: Reduce and potentially turnaround the recent volume and share decline[;] Enhance loyalty to OxyContin among loyalist prescribers[;] Convert 'fence sitters' into more loyal OxyContin prescribers[;] Capture full in-label potential of new formulation among appropriate patients[; and] Protect OxyContin's market share against new market entrants[.]"

- 43. MCKINSEY's deliverables for the project included: "Understanding of drivers of recent decline in category size and market share," "Brand positioning (target segments, frame of reference, reason for differentiation) to maintain and enhance brand loyalty in appropriate patients," and "List of customer issues about new formulation and potential approaches to mitigate concerns[.]"
- 44. In July 2009, MCKINSEY prepared a confidential memorandum for Purdue Pharma Executive 1 with ideas to "chart the course for the 'New [Purdue Pharma]." MCKINSEY wrote that "[Purdue Pharma] must ... drive the OxyContin franchise[.]" MCKINSEY wrote that "driving a more impactful OxyContin franchise should be your top priority." MCKINSEY advised Purdue Pharma to create a small working group to, among other things, "[e]nsure everything is done to optimize and protect OxyContin's positioning[.]" Purdue Pharma should "[b]alance the drive for outsized growth and profitability against the potential for increased regulatory scrutiny and/or compromised exclusivity; adjust sales and marketing plans appropriately[.]" The memo concluded: "It has been our distinct privilege to play a small part in [Purdue Pharma's] progress."

Agreed Statement of Facts

45. In an email dated July 7, 2009, concerning a "Brand Loyalty Project" for OxyContin, Purdue Pharma Executive 2 wrote to MCKINSEY: "I want to be clear that the overall goal of this project is to provide us with recommendations on what we should be doing to support OxyContin (current and new formulation) from both a sales and marketing perspective... regardless of what we think legal may or may not say. The only exception here is what we would test from a messaging perspective." He added: "At the appropriate time, we will have all the necessary conversations with med, reg, and legal to make sure we are promoting the product within FDA regulations."

- 46. In a "brand loyalty" presentation to Purdue Pharma dated September 11, 2009, MCKINSEY presented its findings on "drivers" of brand loyalty, including "opportunities" to promote messages to make prescribers more comfortable prescribing OxyContin. MCKINSEY identified "issues" with OxyContin's brand, including: "Has a reputation for being abused and diverted" and "[i]s medication patients are reluctant to take."
- 47. MCKINSEY laid out for Purdue Pharma "[p]otential reasons why greater number of patients are discontinuing use of [OxyContin] and opioids," including: "Physician and patient perceptions of OER [oxycodone extended-release] is changing (e.g., concerns about)." In an effort to address these negative perceptions, MCKINSEY proposed to "interrogate physicians through phone and in-depth interviews."
- 48. Based on its research concerning the negative perceptions and to improve sales, MCKINSEY developed a "Physician Segmentation" initiative to target specific